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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,657	06/28/2001	Jennifer L. Hillman	PF-0421-2 DIV	1636

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EXAMINER
HARRIS, ALANA M

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/894,657	Applicant(s) HILLMAN ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-III. Claims 1, 2, 16, 17 and 45-47, drawn to an isolated polypeptide, wherein the said polypeptide is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 530, subclass 350.

IV-VI. Claims 3-7, 9, 11, 12 and 48-50, drawn to an isolated polynucleotide, wherein the said polynucleotide is SEQ ID NO: 2 (APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 536, subclass 23.1.

VI-IX. Claim 8, drawn to a transgenic organism comprising a polynucleotide, wherein the said polynucleotide is SEQ ID NO: 2 (APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 800, subclass 21.

X-XII. Claims 10, 30, 31, 33, 35-42, 51 and 52, drawn to an isolated antibody that specifically binds to a polypeptide, wherein the said polypeptide is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 530, subclass 387.1.

XIII-XV. Claim 13, drawn to a method for detecting a target polynucleotide via hybridization, said polynucleotide having a sequence of SEQ ID NO: 2

(APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 435, subclass 6.

XVI-XVIII. Claim 15, drawn to a method for detecting a target polynucleotide via polymerase chain reaction amplification, said polynucleotide having a sequence of SEQ ID NO: 2 (APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 435, subclass 91.2.

XIX-XXI. Claim 18, drawn to a method for treating a disease/condition comprising administering to a patient a composition comprising a polypeptide, wherein in the sequence is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 514, subclass 2.

XXII-XXIV. Claims 19, 22, 25 and 26, drawn to a method for screening a compound for effectiveness as an agonist/antagonist comprising exposing a sample comprising a polypeptide, wherein the polypeptide is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 435, subclass 7.1.

XXV-XXVII. Claims 20 and 23, drawn to a composition comprising an agonist/antagonist identified by the methods utilizing a polypeptide which is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 530, subclass 350.

XXVIII-XXX. Claims 21 and 24, drawn to a method for treating a disease/condition comprising administering to a patient a composition

comprising an agonist/antagonist identified by the methods utilizing a polypeptide which is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 436, subclass 86.

XXXI-XXXIII. Claim 27, drawn to a method for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein the said polynucleotide is SEQ ID NO: 2 (APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 435, subclass 6.

XXXIV-XXXVI. Claim 28, drawn to a method for assessing toxicity of a test compound comprising using a probe polynucleotide, wherein the said polynucleotide is SEQ ID NO: 2 (APOP-1); SEQ ID NO: 4 (APOP-2); and SEQ ID NO: 6 (APOP-3), respectively, classified in class 424, subclass 9.2.

XXXVII-XXXIX. Claims 29, 43 and 44, drawn to a diagnostic test comprising using an isolated antibody that specifically binds to a polypeptide, wherein the said polypeptide is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 436, subclass 512.

XL-XLII. Claims 32 and 34, drawn to a method of diagnosing a condition/disease administering comprising a composition of an isolated antibody that specifically binds to a polypeptide, wherein the said

polypeptide is SEQ ID NO: 1 (APOP-1); SEQ ID NO: 3 (APOP-2); and SEQ ID NO: 5 (APOP-3), respectively, classified in class 514, subclass 8.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-XII and XXV-XVII are structurally and functionally different products, which are made by different methods and have different uses.

The methods of Groups XIII-XXIV and XXXVII-XXX differ in the method objectives, method steps and parameters and in the reagents used. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions of Groups XXVIII-XXX and Groups XIII-XXIV, XXXI-XLII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XXVIII-XXX are drawn to *in vivo* methods and Groups XIII-XXIV and XXXI-XLII are drawn to *in vitro* methods.

Inventions Groups XIII-XVIII, XXXI-XXVI and Groups XIX-XXIV, XXVIII-XXX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups XIII-XVIII, XXXI-XXVI involve the use of polynucleotides, whereas the Groups of XIX-XXIV, XXVIII-XXX involve the use of polypeptides.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to David G. Streeter, Ph.D. on September 30, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA HARRIS
PATENT EXAMINER

Alana M. Harris, Ph.D.
September 30, 2002